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EXAMINER

HM12/0309

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1627
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File copy

Office Action Summary

Application No.

09/246,468

Applicant(s)

Rebek et al

Examiner

Maurie E. Garcia, Ph. D.

Group Art Unit

1627



☒ Responsive to communication(s) filed on Dec 19, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- ☒ Claim(s) 1-15 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-15 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The Response filed December 19, 2000 (Paper No. 10) is acknowledged. No claims were cancelled or added and claim 1 was amended. Therefore, claims 1-15 are pending.

Withdrawn Rejections/Objections

2. The previous rejections under 35 USC 102 are withdrawn in view of applicant's amendments to the claims. The objections to claim 15 are also withdrawn.

Claim Rejections - 35 USC § 101/112 - Lack of Specific Utility

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-15 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well-established utility.

6. According to the text of 35 USC sec. 101, an invention must be “useful”. Our reviewing courts have applied the labels, “specific utility” (or “practical utility”) to refer to this aspect of the “useful invention” requirement of sec. 101. (Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980)). In Nelson, the Court characterized “specific utility” (or “practical utility”) as “a shorthand way of attributing real-world value to claimed subject matter. In other words[, the claimed subject matter will be deemed to have utility if one skilled in the art can use the] claimed discovery in a manner which provides some immediate benefit to the public.” (Id. at 856.)

7. The only utility disclosed for the instant compounds is that they can be used as core molecules for use in constructing a combinatorial library. These libraries are further screened to determine whether - or not - any of the compounds contained within the libraries possess some exploitable biological activity. See, for example, the instant specification, page 4, line 14 through page 5, line 2; page 6, lines 4-11; and page 13, line 12 through page 14, line 3. Therefore, the issue for the claimed compounds under this statute is whether the fact that the claimed compounds can be used to create combinatorial libraries that can be screened, without more, constitutes an “immediate benefit to the public”. The analysis proceeds on two levels. On a first level, an issue is whether any of the claimed compounds are of an immediate benefit to the public. On a second level, an issue is whether the claimed use of the compounds as core molecules for constructing a combinatorial library represents a specific asserted utility. As will be seen from the following discussion, the claimed compounds provide no

immediate benefit to the public and the claimed use does not qualify as a specific asserted utility.

8. With respect to the individual compounds, it is clear that the specification discloses no specific exploitable biological (or other) activity for any of the compounds that would render them of an immediate benefit to the public. The specification suggests that libraries of such compounds be screened for such activity, but does not report that any of the compounds possess an exploitable activity.¹ On the contrary, whether any of the compounds possess such an activity is entirely speculative. Indeed, it is possible, according to the specification as a whole, that none of the compounds will turn out to have any useful activity. Applicants have left to others this burden of determining by means of screening whether any of the compounds will amount to more than mere objects of scientific inquiry². Therefore, as to the individual compounds, there is no disclosed specific utility.

9. On the second level of analysis, the claimed use of the compounds as core molecules for constructing a combinatorial library also would not provide an immediate benefit to the public as such is not a specific asserted utility. The specification states that

¹ Had the specification taught that any of the compounds had a useful activity, then those compounds would be of immediate benefit to the public. The other compounds would then enjoy a rebuttable presumption that they also possess the specified activity. The burden would be on the USPTO to assert, by a preponderance of the evidence, that the proposed utility is not credible. MPEP 2107.

² Note, because the claimed invention is not supported by a specific asserted utility for the reasons just set forth, credibility cannot be assessed.

the benefit that the libraries provide the public is their usefulness as “research tools.” See the specification, at page 13, lines 12-13, and elsewhere: “A combinatorial library of this invention is useful for rapidly generating and developing large numbers of drug candidate molecules.” While research tools have long been recognized as being patentable subject matter, there is also a well-recognized distinction between research tools and the objects of research. Thus, while telescopes, microscopes, gas chromatographs, screening assays, and the like, are examples of research tools that enjoy unquestioned utility (MPEP 2107(I) second column), chemical entities, with no disclosed (and no generally well known) useful activity do not.

10. Thus, one must distinguish between inventions that have a specifically identified utility and inventions whose specific utility requires further research to identify or reasonably confirm. The claimed compounds (and combinatorial libraries made therefrom) fall into this latter category. Giving them labels such as “research tool,” “intermediate” or “for research purposes” does not without more impart specific utility to the invention if, by such labels, it is meant that the invention is merely the object of further research. MPEP 2107(I), second column. As the claimed compounds (and the libraries made therefrom) are in practice objects of further research, they cannot fairly be characterized as “research tools” in the same sense as a microscope or gas chromatograph. Therefore, on the second level of analysis, the claimed compounds do not have a specific asserted utility.

11. In the absence of an asserted specific utility, the “useful” requirement may be established by reference to a well-established utility. MPEP 2107.01(II)(B). A “well established utility” is a “specific utility” which is well known, immediately apparent and implied by the specification based on the disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. The claimed compounds are not supported by a well-established utility, however, because neither the specification as filed nor any art of record discloses or suggests any property or activity for the compounds such that another non-asserted utility would be well established for the compounds. Further, the compounds are not recognizable as analogous to compounds with a recognized pharmacological (or other) activity. In the absence of any data as to their activity, there is no basis upon which to base either a specific or a well-established utility.³ However, the following should be noted as it pertains to the art cited below.

12. The base structure of the claimed core compound (where R and R₁ = H) is well known in the art but has no well-established utility of its own, being as this compound has been used in a variety of other syntheses (for example, see US 3,071,591, cited previously). It should be noted that the prior art teaches using this compound to create

³ Note that a “well established utility” cannot alternatively be based upon a “throw away” utility that one can dream up for an invention, or upon a utility that would obviously apply to virtually every member of a very general class of materials. If this were the case, any product or apparatus, including perpetual motion machines, would have a “well established utility” as landfill, an amusement device, a toy, or a paper weight, any carbon containing molecule would have a “well established utility” as a fuel since it can be burned, and any protein would have well established utilities such as manufacturing supplements for vitamins or food, as protein supplements for animal food, or as an animal poison in the protein is toxic. This is clearly not the intention of the statute.

compounds that have completely different substituent patterns than those set forth in claims 3 and 5-15 and therefore would not suggest that the claimed compounds had similar activity to those compounds known in the prior art. Additionally, the core compound and several variants are known in the art as starting materials for the creation of synthetic host molecules (for example, see Smeets et al, cited previously). These synthetic host molecules represent research tools for studying host-guest chemistry, which also does not constitute a patentable well-established utility.

13. Claims 1-15 also remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Arguments

14. Applicant's arguments filed December 19, 2000 have been fully considered but they are not persuasive. The arguments do not rise to the level of factual evidence. Arguments of counsel alone cannot take the place of evidence in the record.

15. As stated in the rejection, an asserted utility must be specific, not general. The statement of the utility must fully and clearly explain why the applicant believes the invention is useful. Applicant asserts in the Response (page 3) that the compounds have

utility as “a scaffolding upon which large numbers of compounds can be affixed”. This is a general statement. That is, what compounds can be affixed, and for what purpose?

16. Applicant also states that it is “immaterial whether the constructed library is shown to have diagnostic, therapeutic or any other utility”. As stated above, this does **not** clearly explain why the applicant believes the invention (claimed compound) is useful. The claimed compounds are simply an object for further study and there is insufficient disclosed likelihood that any of the claimed compounds would exhibit any useful characteristics. Thus it **is** material that the claimed compound itself have a patentable utility to satisfy 35 USC 101 and 112.

17. Applicants state that the claimed compounds are “analogous to any other scaffold, such as a coded bead, a chromatography column and the like”. The claimed compounds are **not** shown to have a general use as a “scaffold” in the sense that a chromatography column is a “scaffold”. Moreover, even “any other scaffold” must have a patentable utility to comply with the requirements under 35 USC 101 and 112. Therefore, this does not rebut the fact that the claimed compounds must have a specific asserted or well-established utility.

18. Since the examiner maintains that the claimed compounds are not supported by either a specific asserted utility or a well established utility, the rejection of the claims

under 35 USC 112 is also maintained as one skilled in the art clearly would not know how to use the claimed invention.

Status of Claims/Conclusion

19. No claims are allowed.

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:30 to 7:00 and alternate Fridays.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BENNETT CELSA
PRIMARY EXAMINER

sub re

Marta
Am

Maurie E. Garcia, Ph.D.
March 8, 2001